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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,862	12/13/2001	Mark G. Obukowicz	PHA 4140.7	4101
321 7590 12/24/2003 SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			EXAMINER MELLER, MICHAEL V	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/022,862

Applicant(s)

OBUKOWICZ ET AL.

Examiner

Michael V. Meller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 58, 60, 97-105 and 113-128 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 58, 60, 97-105 and 113-128 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.  
37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

The election of species of record is maintained for the reasons of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

Claims 1-3, 58, 60, 97, 98, 100, 104, 105, 113-128 are rejected under 35 U.S.C. 102(b) as being anticipated by La Hann.

The reference teaches that an ethanol extract of capsaicin is administered parenterally to treat pain, see claims. It is inherent that the extract will inhibit COX-2.

LaHann treats pain. Pain is caused by the COX-2 enzyme. It is well known and many medications are well known in the art that inhibit the COX-2 enzyme for the treatment of pain. Thus, if one treats pain, one will inhibit the COX-2 enzyme.

The claims read on administering the extract to anyone.

Claims 1-3, 58, 60, 97, 98, 100, 104, 105, 113-128 are rejected under 35 U.S.C. 102(b) as being anticipated by Byas-Smith.

The reference teaches that an ethanol extract of capsaicin is administered orally to treat pain, see col. 4-7, 9. It is inherent that the extract will inhibit COX-2.

The above comments are also reiterated. Applicants argument are the same as above. Applicants comments concerning that the reference teaches arthritis are noted. Applicant is correct and the reference itself does not teach arthritis but the patent does mention that capsaicin is well known to be used to treat arthritis (col. 4).

The claims read on administering the extract to anyone.

Claims 1-3, 58, 60, 97, 98, 100, 104, 105, 113-128 are rejected under 35 U.S.C. 102(e) as being anticipated by De Lucca, II et al.

The reference teaches that a methanol extract of capsaicin is administered parenterally or orally to treat pain (col. 6). It is inherent that the extract will inhibit COX-2.

Applicants argue what is above. Applicants also argue that the CAY-1 produced is a single compound purified to homogeneity. Applicants claims do not exclude CAY-1. They encompass it since it is an extract from the claimed plant. The reference administers the extract as applicant has done. Thus, the same process is taught in the reference as claimed. The reference does teach the oral and parental administration of the extract, see col. 6.

The claims read on administering the extract to anyone.

***Claim Rejections - 35 USC § 103***

Claims 1-3, 58, 60, 97-105, 113-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Lucca, II et al. or Byas-Smith taken with Hawley's Condensed Chemical Dictionary.

It is clear that the extracts are orally or parenternally administered in the references. It is inherent that the extracts will inhibit COX-2. Applicant argues that there is nothing in the references to show that they treat arthritis, but the claims do not require this. The claims only state a patient, the claims never specify that the patient has the disorder, thus the extract could be given to anybody whether they have the condition or not.

The applicants have submitted similar arguments as discussed above.

The claims read on administering the extract to anyone.

Claims 1-3, 58, 60, 97-105, 113-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Lucca, II et al. or Byas-Smith taken with La Hann and Hawley's Condensed Chemical Dictionary.

It is clear that the extracts are orally or parenternally administered in the references. It is inherent that the extracts will inhibit COX-2. Applicant argues that there is nothing in the references to show that they treat arthritis, but the claims do not require this. The claims only state a patient, the claims never specify that the patient has the

disorder, thus the extract could be given to anybody whether they have the condition or not.

LaHann shows that the extract is noted specifically for treating pain.

The arguments presented are the same as discussed above. Whether the compounds are purified or not they still meet the claims.

The claims read on administering the extract to anyone.

Claims 1-3, 58, 60, 97-105, 113-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holt et al., Stevens, Barr et al. or Caruso in view of La Hann taken with Hawley's Condensed Chemical Dictionary.

It is clear that the extracts are orally or parenternally administered in the references. It is inherent that the extracts will inhibit COX-2. Applicant argues that there is nothing in the references to show that they treat arthritis, but the claims do not require this. The claims only state a patient, the claims never specify that the patient has the disorder, thus the extract could be given to anybody whether they have the condition or not.

LaHann shows that the extract is noted specifically for treating pain.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argues that Holt et al., Stevens, Barr et al. and Caruso do not teach administering the composition as claimed but this is why they are used in a 35 USC 103 rejection. The secondary reference show that it is well within the purview of the skilled artisan to administer the extract as claimed.

The claims read on administering the extract to anyone.

Claims 1-3, 58, 60, 97-105, 113-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over La Hann taken with Hawley's Condensed Chemical Dictionary.

It is clear that the extracts are orally or parenternally administered in the references. It is inherent that the extracts will inhibit COX-2. Applicant argues that there is nothing in the references to show that they treat arthritis, but the claims do not require this. The claims only state a patient, the claims never specify that the patient has the disorder, thus the extract could be given to anybody whether they have the condition or not.

The applicants have submitted similar arguments as discussed above.

The claims read on administering the extract to anyone.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE**

**FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



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A handwritten signature in black ink, appearing to read 'M. V. Meller', followed by a long horizontal line extending to the right.

Michael V. Meller  
Primary Examiner  
Art Unit 1654

MVM